UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JURGEN ROMISCH, ANNETTE FEUSSNER, CHRISTIAN KANNEMEIER and HANS-ARNOLD STOHR

Appeal No. 2006-0565
Application No. 10/033,777

HEARD: APRIL 27, 2006

Before SCHEINER, GRIMES, and GREEN, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1, 3 and 5-21.[1] Claims 1 and 3 are representative of the subject matter on appeal, and read as follows:

[1] Appellants assert that the appeal involves claims 1-21, acknowledging that claims 22-24 were withdrawn from consideration as being drawn to a non-elected invention. See Reply Brief, page 2. As noted by the examiner, however, appellants elected the species drawn to tranexamic acid and a nonionic detergent. See Examiner's Answer, page 3. As claims 2 and 4 are drawn exclusively to the use of an ionic detergent, those claims also stand withdrawn from consideration. Thus, this opinion applies to the claims as they read on the use of tranexamic acid and a nonionic detergent.

1. A stabilized liquid preparation comprising:

   a. a protease or its proenzyme, wherein the protease or its proenzyme activates blood coagulation factor VII;

   b. at least one compound selected from the group consisting of ornithine, diaminopimelic acid, agmatine, creatine, guanidinoacetic acid, acetylornithine, citrulline, arginosuccinic acid, tranexamic acid, and ε-aminocaproic acid or their salts and derivatives; and

   c. wherein said preparation has a pH from 2.0 to 8.0.

3. The stabilized liquid preparation of claim 1, which additionally comprises at least one nonionic detergent.

Claims 1, 3 and 5-21 stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Roemisch JP[2] or Römisch EP,[3] Sato,[4] and Roy[5] or Kessler.[6] After careful review of the record and consideration of the issues before us, we reverse.

DISCUSSION

Claim 1, as examined, is drawn to a stabilized liquid composition comprising a protease or its proenzyme, wherin the protease or its proenzyme activates blood coagulation factor VII, and tranexamic acid, wherein the preparation has a pH from 2.0 to 8.0. See Response Dated April 10, 2003, page 2 (electing the species of tranexamic acid).

---

[2] Roemisch et al. (Roemisch JP), JP 2000-023696, published January 25, 2000.
[3] Römisch et al. (Römisch EP), EP 0952215 A2, published October 27, 1999.
[4] Sato et al. (Sato), US 4,465,662, issued August 14, 1984.
[5] Roy et al. (Roy), US 5,589,363, issued December 31, 1996.
[6] Kessler et al. (Kessler), US 5,604,202, issued February 18, 1997.

Roemisch JP or Römisch EP[7] are relied upon for teaching that a protease that activates blood coagulation factor VII may be stabilized using sodium citrate. See Examiner's Answer, page 4.

Sato is cited for teaching "that tranexamic acid is stabilized using CMC and carragennan [sic] (example 4) and also shows using a protease with it (col. 3, lines 6-23)." Id.

Roy and Kessler are cited by the examiner for teaching that ingredients such as detergents, sugar and amino acids "are known in the art to stabilize compositions such as the claimed invention." Id. at 5.

Thus, according to the examiner, "since the components are used individually in the art for the same purpose to stabilize a composition, then it would have been obvious to use them together to produce a stabilized composition." Id.

Appellants argue that while Sato teaches the use of tranexamic acid in an oral composition for periodontosis prophylaxis, the reference does not teach or suggest its use with a protease capable of activating blood coagulation factor VII or its proenzyme. See Appeal Brief, page 11. In fact, according to appellants, Sato teaches that oral compositions containing tranexamic acid are unstable, and thus it is unclear how it is combined with Roemisch JP or Römisch EP. See id. We agree, and the rejection is reversed.

---

[7] Römisch EP appears to be an English language equivalent of Römisch JP, thus we have focused our review on that reference, as both references are relied upon for the same teaching.

"[T]he Examiner bears the burden of establishing a prima facie case of obviousness based upon the prior art. '[The Examiner] can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references.'" In re Fritch, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (citation omitted). An adequate showing of motivation to combine requires "evidence that 'a skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.'" Ecolochem, Inc. v. Southern Calif. Edison Co., 227 F.3d 1361, 1375, 56 USPQ2d 1065, 1076 (Fed. Cir. 2000).

Römisch EP teaches a protease that activates blood clotting factor VII, and teaches that the protease may be stabilized with sodium citrate. See id. at 2. The reference also teaches that stabilizers such as glutamate, amino acids, calcium ions and sugars may also be used. See id. at 3. The Römisch EP reference fails to teach the use of tranexamic acid as a stabilizer.

Sato teaches that tranexamic acid is a well known anti-inflammatory agent and hemostyptic agent, but teaches that oral compositions containing it are unstable and tend to discolor upon aging. See id. at Column 1, lines 6-21. The reference teaches that the composition may be stabilized by the addition of other materials, such as carvone. See id. at Column 2, lines 47-55. According to Sato, the composition may contain other ingredients such as "enzymes such as

amylase, protease, mutanase, lysozyme, lytic enzyme, etc." Id. at Column 3, lines 9-13.

Thus, we can find nothing in either Römisch EP or Sato that would suggest to one of ordinary skill in the art to add tranexamic acid to the protease of Römisch EP as Sato in fact teaches that compositions containing tranexamic acid are unstable, and teach methods of stabilizing the composition. Nor does the examiner point to, nor do we find, anything in Roy or Kessler that would remedy that deficiency. Thus, the combination does not suggest adding the tranexamic acid as taught by Sato to the protease taught by Römisch EP to stabilize the protease as set forth in the rejection, and the rejection must be reversed.

The examiner argues, citing example 4, "that Sato found the tranexamic acid to stabilize compositions." Examiner's Answer, page 5. Example 4 states, however, "that the aging stability of tranexamic acid-containing compositions is improved when CMC and carrageenan are blended at a ratio of 6:4 to 10:0." Id. at Column 7, lines 56-59. Thus again, the tranexamic acid is being stabilized in the example, and not acting as a stabilizer.

CONCLUSION

Because the examiner has failed to set forth a prima facie case of obviousness, the rejection of record is reversed.

REVERSED

Toni R. Scheiner)
Administrative Patent Judge)
)
)
Eric Grimes) BOARD OF PATENT
Administrative Patent Judge) APPEALS AND
)
Lora M. Green) INTERFERENCES
Administrative Patent Judge)

LMG/jlb

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON DC 20001-4413